

CLAIMS

1. A pharmaceutical composition for the treatment of anorectal or colonic diseases such as hemorrhoids, fissures, cracks, fistulas, abscesses, inflammatory bowel disease, and the like comprising of an extract of the plant *Euphorbia prostrata* containing flavonoids and phenolic compounds, wherein the flavonoids are apigenin-7-glycoside, 1 - 4% by weight; luteolin-7-glycoside, 0.3 - 2% by weight; and apigenin, luteolin and quercetin, 0.001 - 0.3% by weight; and wherein the phenolic compounds are ellagic acid, 1-15% by weight; gallic acid, 1 - 12% by weight and tannins, 1 - 10% by weight; optionally with additional therapeutic agent(s); and wherein the pharmaceutical composition comprise of the extract of the plant *Euphorbia prostrata* from about 0.1% to about 99% by weight.
2. The pharmaceutical composition as claimed in claim 1, wherein the extract comprises 2.5 - 3.5% by weight apigenin-7-glycoside, 0.5 - 1.5% by weight luteolin-7-glycoside, 0.05 - 0.2% by weight apigenin, luteolin and quercetin, 4 - 15% by weight ellagic acid, 4 - 12% by weight gallic acid and 3 - 8% by weight tannins.
3. The pharmaceutical composition as claimed in claims 1 and 2, wherein the composition further comprises pharmaceutically acceptable carrier(s)/base(s).
4. The pharmaceutical composition as claimed in claims 1 to 3, comprising additional therapeutic agent(s), selected from astringents, anesthetics, vasoconstrictors, protectants, counterirritants, keratolytics, anti-cholinergics, wound healing agents and anti-microbial agents, or their pharmaceutically acceptable salts; used either alone or in combination thereof.
5. The pharmaceutical composition as claimed in claim 4, wherein the additional therapeutic agent is an astringent.

6. The pharmaceutical composition as claimed in claim 5, wherein the astringent is selected from calamine, zinc oxide, hamamelis water, bismuthresorcinol compound, bismuth subgallate, Peruvian balsam, aluminium chlorohydroxy allantoinate, tannic acid, and the like; used
5 either alone or in combination thereof.
7. The pharmaceutical composition as claimed in claim 6, wherein the amount of the astringent varies between 0.2% and 60% by weight.
8. The pharmaceutical composition as claimed in claim 4, wherein the additional therapeutic agent is an anesthetic.
- 10 9. The pharmaceutical composition as claimed in claim 8, wherein the anesthetic is selected from benzocaine, diperomon, pramoxine, camphor, dibucaine, phenol, tetracaine, phenacaine, and the like; used either alone or in combination thereof.
10. The pharmaceutical composition as claimed in claim 9, wherein the
15 amount of the anesthetic varies between 0.25% and 25% by weight.
11. The pharmaceutical composition as claimed in claim 4, wherein the additional therapeutic agent is a vasoconstrictor.
12. The pharmaceutical composition as claimed in claim 11, wherein the vasoconstrictor is selected from ephedrine or phenylephrine; used
20 either alone or in combination thereof.
13. The pharmaceutical composition as claimed in claim 12, wherein the amount of the vasoconstrictor varies between 0.005% and 1.5% by weight.
14. The pharmaceutical composition as claimed in claim 4, wherein the
25 therapeutic agent is a counterirritant.
15. The pharmaceutical composition as claimed in claim 14, wherein the counterirritant is menthol and is present an amount between 0.25 and 2.5%.

16. The pharmaceutical composition as claimed in claim 4, wherein the therapeutic agent is a protectant.
17. The pharmaceutical composition as claimed in claim 16, wherein the protectant is selected from aluminium hydroxide gel, calamine, cocoa butter, cod or shark liver oil, starch, white petroleum, wool alcohol, zinc oxide, vegetable or castor oil, polyethylene glycol, propylene glycol, and the like; used either alone or in combination thereof.
18. The pharmaceutical composition as claimed in claim 17, wherein the protectant is present in an amount between 5.0% and 88.0% by weight.
19. The pharmaceutical composition as claimed in claim 4, wherein the therapeutic agent is a wound healing agent.
20. The pharmaceutical composition as claimed in claim 19, wherein the wound healing agent is selected from vitamin A, vitamin D, Peruvian balsam, cod liver oil and the like; used either alone or in combination thereof.
21. The pharmaceutical composition as claimed in claim 20, wherein the vitamin A and/or vitamin D are present in an amount between 0.005% to 0.04% by weight.
22. The pharmaceutical composition as claimed in claim 20, wherein the Peruvian balsam is present in an amount between 0.5% to 2.5% by weight.
23. The pharmaceutical composition as claimed in claim 20, wherein the cod liver oil is present in an amount between 1.0% to 6.0% by weight.
24. The pharmaceutical composition as claimed in claim 4, wherein the therapeutic agent is an antimicrobial agent.

25. The pharmaceutical composition as claimed in claim 24, wherein the antimicrobial agent is selected from benzethonium chloride, benzalkonium chloride, boric acid, 8-quinolinol benzoate, secondary amyltr cresols, cetylpyridinium chloride, phenol, menthol, chlorothymol, camphor and 8-hydroxyquinoline sulfate and the like; used either alone or in combination thereof.
26. The pharmaceutical composition as claimed in claim 25, wherein the antimicrobial agent is present in an amount between 0.02% and 40% by weight.
27. The pharmaceutical composition as claimed in claim 4, wherein the therapeutic agent is a keratolytic.
28. The pharmaceutical composition as claimed in claim 27, wherein the keratolytic is selected from aluminium chlorohydroxy allantoinate and resorcinol, used either alone or in combination thereof.
29. The pharmaceutical composition as claimed in claim 28, wherein the keratolytic is present in an amount between 0.2% and 3.5% by weight.
30. The pharmaceutical composition as claimed in claim 4, wherein the therapeutic agent is an anticholinergic.
31. The pharmaceutical composition as claimed in claim 30, wherein the anticholinergic is selected from atropine or other solanaceous type alkaloids; used either alone or in combination thereof.
32. The pharmaceutical composition as claimed in claim 31, wherein the amount of the anti-cholinergic varies between 0.02% and 0.1% by weight.
33. The pharmaceutical composition as claimed in claim 1, wherein the composition is in the form of a cream, ointment, solution, spray, foam, suppository, medicated pad, bandage, powder, suspension, film, flake, oral hard gelatin capsules, soft gelatin capsules, tablets

(coated and uncoated), modified release dosage form, liquid, lozenges, buccal or sublingual dosage form, wafers, caplets, or parenteral dosage form to be infiltrated at the site of the injection.

34. A process for the preparation of a pharmaceutical composition for the treatment of anorectal or colonic disease such as hemorrhoids, fissures, cracks, fistulas, abscesses and inflammatory bowel disease comprising of an extract of the plant *Euphorbia prostrata* containing flavonoids and phenolic compounds, wherein the flavonoids are apigenin-7-glycoside, 1 - 4% by weight; luteolin-7-glycoside, 0.3 - 2% by weight; and apigenin, luteolin and quercetin, 0.001 - 0.3% by weight; and wherein the phenolic compounds are ellagic acid, 1-15% by weight; gallic acid, 1 - 12% by weight and tannins, 1 - 10% by weight, with pharmaceutically acceptable carrier(s)/base(s) as herein described, optionally with additional therapeutic agent(s) as herein described, comprising of the following steps.
- a. drying the plant *Euphorbia prostrata* under controlled conditions of temperature and humidity,
 - b. making a powder from the dried plant,
 - c. extracting the dry coarse powder with a polar solvent repetitively to form an extract,
 - d. distilling the extract,
 - e. washing the concentrated extract with a non-polar organic solvent, and
 - f. drying the washed extract to produce the desired pharmaceutically acceptable extract capable of being used along with pharmaceutically acceptable carrier(s)/base(s).
35. The process for the preparation of a pharmaceutical composition according to claim 34 wherein the process for the manufacture of the extract further comprises:

- a. re-extracting the washed polar extract in a medium polarity organic solvent,
 - b. distilling the extract,
 - c. dehydrating the extract, and
 - 5 d. drying the extract to produce the desired pharmaceutically acceptable extract capable of being used along with pharmaceutically acceptable carrier(s)/base(s).
36. The process for the preparation of a pharmaceutical composition as claimed in claim 34 and 35, wherein the extract comprises 2.5 – 3.5%
10 by weight apigenin-7-glycoside, 0.5 – 1.5% by weight luteolin-7-glycoside, 0.05 – 0.2% by weight apigenin, luteolin and quercetin, 4 – 15% by weight ellagic acid, 4 – 12% by weight gallic acid and 3 – 8% by weight tannins.
37. The process for the preparation of a pharmaceutical composition as
15 claimed in claims 34 to 36, wherein the pharmaceutical composition comprises additional therapeutic agent(s), selected from astringents, anesthetics, vasoconstrictors, protectants, counterirritants, keratolytics, anti-cholinergics, wound healing agents and anti-microbial agents, or their pharmaceutically acceptable salts; used
20 either alone or in combination thereof.
38. The process for the preparation of a pharmaceutical composition as
claimed in claim 37, wherein the additional therapeutic agent is an astringent.
39. The process for the preparation of a pharmaceutical composition as
25 claimed in claim 38, wherein the astringent is selected from calamine, zinc oxide, hamamelis water, bismuthresorcinol compound, bismuth subgallate, Peruvian balsam, aluminium chlorohydroxy allantoinate, tannic acid; used either alone or in combination thereof.

40. The process for the preparation of a pharmaceutical composition as claimed in claim 39, wherein the amount of the astringent varies between 0.2% and 60% by weight.
- 5 41. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the additional therapeutic agent is an anesthetic.
42. The process for the preparation of a pharmaceutical composition as claimed in claim 41, wherein the anesthetic is selected from benzocaine, diperomon, pramoxine, camphor, dibucaine, phenol, 10 tetracaine, phenacaine; used either alone or in combination thereof.
43. The process for the preparation of a pharmaceutical composition as claimed in claim 42, wherein the amount of the anesthetic varies between 0.25% and 25% by weight.
- 15 44. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the additional therapeutic agent is a vasoconstrictor.
45. The process for the preparation of a pharmaceutical composition as claimed in claim 44, wherein the vasoconstrictor is selected from ephedrine or phenylephrine; used either alone or in combination 20 thereof.
46. The process for the preparation of a pharmaceutical composition as claimed in claim 45, wherein the amount of the vasoconstrictor varies between 0.005% and 1.5% by weight.
- 25 47. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the therapeutic agent is a counterirritant.

48. The process for the preparation of a pharmaceutical composition as claimed in claim 47, wherein the counterirritant is menthol and is present an amount between 0.25 and 2.5%.
49. The process for the preparation of a pharmaceutical composition as
5 claimed in claim 37, wherein the therapeutic agents is a protectant.
50. The process for the preparation of a pharmaceutical composition as
claimed in claim 49, wherein the protectant is selected from
aluminium hydroxide gel, calamine, cocoa butter, cod or shark liver
oil, starch, white petroleum, wool alcohol, zinc oxide, vegetable or
10 castor oil, polyethylene glycol, propylene glycol; used either alone or
in combination thereof.
51. The process for the preparation of a pharmaceutical composition as
claimed in claim 50, wherein the protectant is present in an amount
between 5.0% and 88.0% by weight.
- 15 52. The process for the preparation of a pharmaceutical composition as
claimed in claim 37, wherein the therapeutic agent is a wound healing
agent.
53. The process for the preparation of a pharmaceutical composition as
claimed in claim 52, wherein the wound healing agent is selected
20 from vitamin A, vitamin D, Peruvian balsam, cod liver oil; used
either alone or in combination thereof.
54. The process for the preparation of a pharmaceutical composition as
claimed in claim 53, wherein the vitamin A and/or vitamin D are
present in an amount between 0.005% to 0.04% by weight.
- 25 55. The process for the preparation of a pharmaceutical composition as
claimed in claim 53, wherein the Peruvian balsam is present in an
amount between 0.5% to 2.5% by weight.

56. The process for the preparation of a pharmaceutical composition as claimed in claim 53, wherein the cod liver oil is present in an amount between 1.0% to 6.0% by weight.
57. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the therapeutic agent is an antimicrobial agent.
58. The process for the preparation of a pharmaceutical composition as claimed in claim 57, wherein the antimicrobial agent is selected from benzethonium chloride, benzalkonium chloride, boric acid, 8-quinolinol benzoate, secondary amyltr cresols, cetylpyridinium chloride, phenol, menthol, chlorothymol, camphor and 8-hydroxyquinoline sulfate; used either alone or in combination thereof.
59. The process for the preparation of a pharmaceutical composition as claimed in claim 58, wherein the antimicrobial agent is present in an amount between 0.02% and 40% by weight.
60. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the therapeutic agent is a keratolytic.
61. The process for the preparation of a pharmaceutical composition as claimed in claim 60, wherein the keratolytic is selected from aluminium chlorohydroxy allantoinate and resorcinol, used either alone or in combination thereof.
62. The process for the preparation of a pharmaceutical composition as claimed in claim 61, wherein the keratolytic is present in an amount between 0.2% and 3.5% by weight.
63. The process for the preparation of a pharmaceutical composition as claimed in claim 37, wherein the therapeutic agent is an anticholinergic.

64. The process for the preparation of a pharmaceutical composition as claimed in claim 63, wherein the anticholinergic is selected from atropine or other solanaceous type alkaloids; used either alone or in combination thereof.
- 5 65. The process for the preparation of a pharmaceutical composition as claimed in claim 64, wherein the amount of the anti-cholinergic varies between 0.02% and 0.1% by weight.
- 10 66. A method of treatment of anorectal or colonic disease such as hemorrhoids, fissures, cracks, fistulas, abscesses, inflammatory bowel disease, and the like comprising administering an extract of the plant *Euphorbia prostrata* containing flavonoids and phenolic compounds, wherein the flavonoids are apigenin-7-glycoside, 1 - 4% by weight; luteolin-7-glycoside, 0.3 - 2% by weight; and apigenin, luteolin and quercetin, 0.001 - 0.3% by weight; and wherein the
15 phenolic compounds are ellagic acid, 1-15% by weight; gallic acid, 1 - 12% by weight and tannins, 1 - 10% by weight, with pharmaceutically acceptable carrier(s)/base(s); optionally with additional therapeutic agent(s).
- 20 67. Use of an extract of the plant *Euphorbia prostrata* for the preparation of a pharmaceutical composition for the treatment of anorectal or colonic disease such as hemorrhoids, fissures, cracks, fistulas, abscesses, inflammatory bowel disease, and the like.
- 25 68. The pharmaceutical composition for the treatment of anorectal or colonic diseases substantially as herein described and illustrated by the examples.
69. The process for the preparation of a pharmaceutical composition for the treatment of anorectal or colonic diseases substantially as herein described and illustrated by the examples.